

Summary of Safety and Effectiveness

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Excel OneStep Urine/Serum hCG Module Pregnancy Test

Excel OneStep Urine/Serum hCG Module Pregnancy Test is Excel Scientific, Inc.'s name for the professional use of solid phase chromatographic immunoassay *in vitro* diagnostic test kit for the qualitative determination of human chorionic gonadotropin in urine or serum. The exact differences between the Excel OneStep Urine/Serum hCG Module Pregnancy Test and the Syntron Quikpac I enzyme immunoassay, an assay for human chorionic gonadotropin currently being marketed are as follows :

1. The Syntron Quikpac I EIA protocol is a classical sandwich enzyme immunoassay where endogenous hormone hCG, is first bound by antibody covalently linked to a solid membrane. A second enzyme linked antibody is then reacted to the membrane to form antibody-hCG-antibody-enzyme complexes. The complex is reacted with a suitable substance to produce a visible "+" positive when the hCG concentration is greater than 25 mIU/mL; and "-" negative on the center of the membrane indicates the absence of detectable levels of hCG.
2. The Excel OneStep Urine/Serum hCG Module Pregnancy Test is a sandwich solid phase dye-conjugate non-enzyme chromatographic immunoassay. As the specimen flows through the absorbent device via capillary action, the labeled antibody dye conjugate binds to the hCG in the specimen forming an antibody-antigen complex. This complex binds to the anti-hCG antibody immobilized on the membrane in the positive reaction zone and produces a pink-rose color band when the hCG concentration in the specimen is equal to or greater than 25 mIU/mL. In the absence of hCG, no colored line will appear in the positive reaction zone. The reaction mixture continues to flow through the absorbent device past the positive reaction zone and produce a pink-rose color band in the control zone, demonstrating that the reagent and device are functioning correctly.

The exact reagent addition differences between the above two test protocols are as follows:

| | Syntron Quikpac I EIA | Excel OneStep Urine/Serum hCG Module |
|-----------------|--|---------------------------------------|
| Specimen Volume | 5 drops urine 3 drops serum | 4 drops urine 4 drops serum |
| Reagent | 2 bottles for either urine or serum | No reagent for urine or serum |
| Incubation | 3 minutes with antibody and 3 minutes with substrate | No pre-incubation with urine or serum |
| Steps | three | one |
| Cutoff | 25 mIU/mL | 25 mIU/mL |